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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,511	04/26/2001	Hans-Peter Saluz	F-6954	8214

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04/12/2004

Jordan & Hamburg
122 East 42nd Street
New York, NY 10168

EXAMINER

BEISNER, WILLIAM H

ART UNIT

PAPER NUMBER

1744

DATE MAILED: 04/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/830,511

Applicant(s)

SALUZ ET AL.

Examiner

William H. Beisner

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 18 March 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Attachment.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____

Claim(s) objected to: _____

Claim(s) rejected: 1,3-5,7 and 9-13

Claim(s) withdrawn from consideration: _____

8. ☒ The drawing correction filed on 18 March 2004 is a) ☒ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
10. ☐ Other: _____

William H. Beisner
Primary Examiner
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DETAILED ACTION

Response to Arguments

1. See 37 CFR 1.193(a)(2) which provides for the inclusion of the proposed rejection(s) detailed below in the Examiner's Answer if applicant elects to file an appeal to the Board of Patent Appeals and Interferences in this proceeding. To be complete, such rejection(s) must be addressed in any brief on appeal.

Upon appeal and entry of the amendment:

In view of the proposed inclusion of the limitations of claim 12 in claim 1, claims 1, 3-5, 7 and 9-12 would be rejected for the reasons set forth in 35 USC 103(a) rejection over the combination of the references of Tretyakov et al., Dannoux et al. and Sanadi of the final Office Action mailed 17 Nov. 2004.

With respect to the combination of the references of Tretyakov et al., Dannoux et al. and Sanadi, Applicants comment the "The Examiner has merely set forth a possible combination of different features but has failed to show how the references suggest such a combination". Applicants first comment that "The inclusion of a rigid support frame with a plate formed of thin flexible film having an array of wells is not suggested by the art references cited because the incentive to include a frame in the well plate of the Tretyakov reference is absent". Applicants stress that the reference of Tretyakov does not require a support frame because the entire disclosed process is performed in the heat block.

With respect to the reference of Dannoux, Applicants argue that the well forming device of the reference does not permit optical inspection of the contents of the wells and a frame is necessary such that the well plate can be moved to an observation device that is separate from

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the well forming device. Applicants again stress that the reference of Tretyakov permit the "entire PCR cycling" to be done in the heat block having the vacuum apertures and one skilled in the art would see not need to remove the multiwell plate prior to completion of the process.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In this case while the reference of Tretyakov performs the method of forming the plate and the temperature cycling of a sample within the same structure (the heating plate), the reference clearly discloses that further processing of the sample is performed that would occur outside the realm of the heating block. Specifically, the reference of Tretyakov discloses that the thermocycled sample is analyzed using electrophoresis (See page 4 of the English language translation). While the reference of Tretyakov may not specifically suggest the use of a support frame, the reference clearly suggests further processing of the sample is performed in addition to the thermal cycling within the heater block. The suggestion required of Applicants is provided by the reference of Dannoux. The reference of Dannoux clearly discloses a well plate "for samples of chemical or biological products". One of ordinary skill in the art would clearly recognize that PCR amplification of a sample would result in a "chemical or biological product". The reference of Dannoux additionally discloses the use of a support frame for the well plate that "facilitates the manual or automatic handling operations of the plate" (See page 8, lines 3-13). As a result, one of ordinary skill in the art would be motivated to provide the well plate structure disclosed by the reference of Tretyakov with a support frame as disclosed by the reference of

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Dannoux for the known and expected advantage of facilitating the manual or automatic handling operations of the plate. In contrast to Applicants comments concerning the disclosure of the reference of Tretyakov, nothing in the disclosure of the reference of Tretyakov would lead one of ordinary skill in the art to think the reference precludes any additional processing steps that would require removal of the well plate from the heating block. In fact the reference of Tretyakov discloses that additional processing steps are performed after the sample is amplified by disclosure of electrophoresis. One of ordinary skill in the art would clearly recognize that when performing PCR amplification further processing steps can be performed, especially analysis steps such as disclosed by the reference of Tretyakov or any other art recognized means for analysis of PCR products.

In response to Applicants' comments concerning the discovery the source/cause of a problem, Applicants comments are not found to be persuasive for the following reasons:

- i) Discovery of the source/cause of a problem does not always result in a patentable invention (See *In re Wiseman*, 201 USPQ 658 (CCPA 1979)).
- ii) Applicants state that the present application has identified a problem and a source of a problem, however, the instant specification as originally filed is silent the problems now raised by applicants. The originally filed disclosure only discusses problems with respect to the thickness and/or shape of the wells and discloses the use of a support frame for the same purposes disclosed by the reference of Dannoux.
- iii) Additionally, Applicants have not provided any evidence by way of affidavits or declarations or by way of clear and persuasive assertion in the specification supporting the stated discovery of a source of a problem (See *In re Wiseman*, 201 USPQ 658 (CCPA 1979)).

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iv) The Examiner is not persuaded that one of ordinary skill in the art would not recognize that an apertureless heater block would provided better heat transfer than one with an aperture.

With respect to the combination of the references of Tretyakov, Dannoux and Sanadi, Applicants argue that the combination is improper because the reference of Sanadi shows a support plate with an array of holes for accepting individual vessels in a spaced relationship and since the well plate of the present invention are formed in a spaced relationship, there is no incentive to use a support plate with an array of holes. Applicants also comment that references do not suggest a reason for the combination.

Applicants' comments are not found to be persuasive because the reference of Sanadi discloses the use of support plate (carrier tray (16)) with an array of openings (17) for supporting a well plate (tube tray (3)). Note the reference of Sanadi discloses that tube tray (3) provides tubes or well-like vessels (4) and that that vessels (4) can be integral with the tray (See column 2, lines 54-65, and column 4, lines 50-66). The tray (3) provides the wells or vessels in a spaced relationship much the same as the wells of the instant invention and those of the reference of Tretyakov, yet, the reference of Sandi still discloses the use of the tray in combination with support plate (16) with an array of openings (17). As a result, the reference of Sanadi does provide incentive to combine the well plate of the reference of Tretyakov for the known and expected result of providing a means to support the well plate for manual or automated handling as suggested by the reference of Dannoux while providing an art recognized structure for preventing contamination of the contents of the well without changing the effective dimensions

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of the assembly so that standardized equipment can still be used (See column 2, lines 42-48, of the reference of Sanadi).

With respect to the rejection of the claims over the combination of the references of Tretyakov, Dannoux and Atwood, Applicants argue nothing in the disclosure of the reference of Tretyakov would provide incentive to change the disclosed arrangement since it is fully functional and there is no identification of a deficiency in the arrangement. Applicants comment that since the well plate of the reference of Tretyakov is so thin, one would be dissuaded from attempting such use because transferring without a support frame is not practical. Applicants also comment that the reference of Dannoux (the Examiner is assuming that reference to Sanadi is meant to be Dannoux in view of Applicants' previous comments) requires removal of the well plate formed in the forming device for its use while the process of the reference of Tretyakov does not require its removal.

In response, the Examiner maintains that the combination of the references of Tretyakov and Dannoux are suggested for the reasons previously set forth above with respect to the same combination of references.

With respect to Applicants' comments concerning the desirability of using an apertureless heating block, the rejection of record provides sound reasoning as to why one of ordinary skill in the art would be motivated to employ a heater block such as that disclosed by the reference of Atwood. Furthermore, the heating block of the reference of Tretyakov discloses the use of holes solely for the purpose of forming the well plate in a similar manner in which the well plate of the reference of Dannoux is formed. Clearly one of ordinary skill in the art would recognize that the well plate formed by the device of Tretyakov can be used in other

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conventionally known heater blocks, especially in view of the disclosure of Dannoux which clearly suggests the formation of the well plate in one device and subsequent use of the well plate in other art recognized devices for processing a chemical or biological sample.

For these reasons, the prior art rejections of record will be maintained upon filing a Notice of Appeal.

Terminal Disclaimer

2. The terminal disclaimer filed on 18 March 2004 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No. 6,556,940 has been reviewed and is accepted. The terminal disclaimer has been recorded.

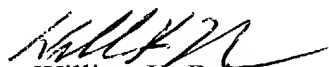
In view of the terminal disclaimer filed 18 March 2004, the obviousness-type double patenting rejections over U.S. Patent No. 6,556,940 have been withdrawn.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



William H. Beisner
Primary Examiner
Art Unit 1744

WHB